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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,081

Applicant(s)

SHAPIRO, LELAND

Examiner

Kathleen M. Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-17, 23-25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 8, 9 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 10, 15 and 30 is/are rejected.
- 7) ☒ Claim(s) 2, 7, 12-14, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on September 25, 2003), Applicants filed a response and amendments received on January 23, 2004 (drawings) and April 5, 2005 (compliant claims). Said amendment cancelled Claims 18-20 and 29 and amended Claim 1, 3, 9, and 14. Thus, Claims 1-10, 12-17, 23-25, and 30 are pending in the instant Office action.

Election

2. As previously noted, Applicants elected methods of treatment using α_1 -antitrypsin, the elected species of serine protease inhibitor. As amended, Claims 1-4, 7, 10, 12-17, and 30 are drawn or contain subject matter drawn to the elected subject matter; Claims 5-6, 8-9, and 23-25 exclude using α_1 -antitrypsin as the serine protease for treatment. Thus, Claims 5-6, 8-9, and 23-25 are withdrawn from further consideration as non-elected inventions, and Claims 1-4, 7, 10, 12-17, and 30 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/123,167 filed on March 5, 1999.

Information Disclosure Statement

4. As previously noted in Paper No. 9, the information disclosure statement filed on May 4, 2001 (Paper No. 3) has not been considered because the references were not filed for

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consideration. Applicants noted that the references have been filed in related cases; this is insufficient unless the related case is a parent application. For these references to be cited on the front page of any patent, copies of the documents must be filed with the instant application.

The IDS filed on June 19, 2000 (Paper No. 2) has been considered as previously noted.

Drawings

5. The drawings filed on January 23, 2004 have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Withdrawn - Objection to the Specification

6. Previous objection to the amendment filed January 29, 2003 (Paper No. 15) under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment to non-elected Claim 9.

Withdrawn - Objections to the Claims

7. Previous objection to Claims 1-4, 7, 10, 12-20, and 29-30 for containing non-elected subject matter is withdrawn by virtue of the Examiner's reconsideration. It is noted, however, that claims drawn to methods of treatment using α_1 -antitrypsin, the elected species of serine protease inhibitor, is the extent of the examination of the claimed invention for prior art purposes.

New - Claim Objections

8. Claims 2, 7, 12-14, 16, and 17 are objected to for depending from rejected claims.

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Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

9. Previous rejection of Claims 1-4, 7, 10, 12-20 and 29-30 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “wasting disease” is withdrawn by virtue of Applicant’s amendment removing said term.

10. Previous rejection of Claims 3-4 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “and combinations thereof” is withdrawn by virtue of Applicant’s amendment removing said phrase.

New - Claim Rejections - 35 U.S.C. § 112, second paragraph

11. Claims 3-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “an oxidation-resistant or free radical-resistant Met³⁵⁸ variants thereof” is confusing. Are both oxidation-resistant and free radical-resistant variants the Met358 variants? Is this limited to Met358 variants of α 1-anti-trypsin wherein only the 358 position is altered? Moreover, the 358 position is a methionine in only one source of α 1-anti-trypsin, is only this variant intended? Clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

12. Previous rejection of Claim 14 under 35 U.S.C. § 112, first paragraph, new matter, for the limitation of “no greater than 200 μ M” is withdrawn by virtue of Applicant’s amendment.

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Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

13. Previous rejection of Claims 3-4 under 35 U.S.C. § 112, first paragraph, written description, for an oxidation-resistant or free radical-resistant Met³⁵⁸ variants is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment has obviated the rejection; the Examiner disagrees as based on the new rejection under 35 U.S.C. § 112, second paragraph above. It is noted that inasmuch as Claims 3 and 4 are limited to a particular α 1-anti-trypsin having a residue other than methionine at position 358, the instant claims have adequate written description.

14. Previous rejection of Claims 3-4 under 35 U.S.C. § 112, first paragraph, scope of enablement, for an oxidation-resistant or free radical-resistant Met³⁵⁸ variants is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment has obviated the rejection; the Examiner disagrees as based on the new rejection under 35 U.S.C. § 112, second paragraph above. It is noted that inasmuch as Claims 3 and 4 are limited to a particular α 1-anti-trypsin having a residue other than methionine at position 358, the instant claims have adequate written description.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

15. Previous rejection of Claims 1-4 and 30 under 35 U.S.C. § 102(b) as being anticipated by Van Molle *et al.* is withdrawn by virtue of Applicant's amendment removing toxin-induced liver injury from the claimed patient for treatment.

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16. Previous rejection of Claims 1, 3, 4, 10, 15, and 30 under 35 U.S.C. § 102(b) as being anticipated by Emerson *et al.* (USPN 4,829,054) is withdrawn by virtue of Applicant's amendment removing sepsis from the claimed patient for treatment.

17. Previous rejection of Claims 1, 3, 4, 10, 12-16, and 30 under 35 U.S.C. § 102(b) as being anticipated by Lezdey *et al.* (USPN 5,532,215) is withdrawn by virtue of Applicant's amendment removing HIV from the claimed patient for treatment.

18. Previous rejection of Claim 18 under 35 U.S.C. § 102(b) as being anticipated by Emerson *et al.* (USPN 4,829,054) as evidenced by Mahidhara *et al.* (Apoptosis and sepsis. Crit. Care Med. (2000) 28:4 (Suppl.)) is withdrawn by virtue of Applicant's cancellation of said claim.

19. Previous rejection of Claims 19-20 under 35 U.S.C. § 102(a) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Van Molle *et al.* is withdrawn by virtue of Applicant's cancellation of said claim.

New - Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claims 1, 3, 4, 10, 15, and 30 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lezdey *et al.* (USPN 6,124,257). The instant claims are drawn to treating a human subject suffering from diabetes with α 1-antitrypsin in a dose of 0.001-70 g/kg body weight given nasally.

Lezdey *et al.* teach methods of treating a patient having a non-pulmonary disease, in particular diabetes, with α 1-antitrypsin (see Claim 4). In column 4, lines 38-47, α 1-antitrypsin is administered to children (i.e., human patients). The range of .001-70 g/kg body weight is taught by the average dosage of 100-200 mg in column 3, lines 57-58. In Example III in column 4, the treatment is by inhalation.

Summary of Pending Issues

21. The following is a summary of the issues pending in the instant application:

- a) Claims 2, 7, 12-14, 16, and 17 stand objected to for depending from rejected claims.
- b) Claims 3-4 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “an oxidation-resistant or free radical-resistant Met³⁵⁸ variants thereof”.
- c) Claims 3-4 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- d) Claims 3-4 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, for an oxidation-resistant or free radical-resistant Met³⁵⁸ variants.
- e) Claims 1, 3, 4, 10, 15, and 30 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lezdey *et al.* (USPN 6,124,257).

Conclusion

22. Claims 2, 7, 12-14, 16, and 17 are objected to. Claims 1, 3, 4, 10, 15, and 30 stand rejected for the reasons identified in the numbered sections of this Office action. Applicants

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must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

June 15, 2005